

REMARKS/ARGUMENTS

This case has been carefully reviewed and analyzed in view of the Office Action dated October 12, 2006. Responsive to the rejections made in the Office Action, Claims 22 and 23 have been canceled without prejudice. Claim 21 has been amended by incorporating the limitation of Claim 23. Claims 25-27 have been amended because claims 22-23 have been canceled. Support for amended claim 21 may be found in original claim 23. No new matter has been added.

Entry of this Amendment is respectfully requested.

During the interview of 1/11/2007 2PM EST initiated by the applicant, the Examiner has suggested the applicant to incorporate claim 22 into claim 21 and cancel claim 23. In addition, a comparison between present invention and Rath US Pat No. 5650418 as well as Rath EP 0815771 was discussed. Further, the lack of example of homocysteine was also discussed.

Claim Rejections – 35 USC § 112, First Paragraph

Pending claim 21, 22, 24-27 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 21 has been amended to remove “2-Lasotene, Latein, Zea-Cryptoxanthin” from the claim.

Accordingly, applicant respectfully requests the rejection be withdrawn.

Claim Rejections – 35 USC § 112, Second Paragraph

Pending claim 21, 22, 24-27 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention . Claim 21 has been amended to remove “2-Lasotene, Latein, Zea-Cryptoxanthin” from the claim.

Accordingly, applicant respectfully requests the rejection be withdrawn.

Claims rejection – 35 USC § 103 (“Rath US’ 418,” “Rath EP’ 771,” “Chochran,” “Life Extension,” “Umbdenstock”)

In the Office Action, the Examiner rejected claims 21, 24-27 and 32 under 35 USC § 103(a) as being obvious over Rath et al. (US 5650418) in view of Rath et al. (EP 0 891771 A1), and further in view of Chochran (US 6048846), Product Information Brochure (Life Extension Mix Multivitamin, 1997) and Umbdenstock (US 5332579).

Applicant respectfully traverses this rejection for the following reasons:

I. Prior art reference Chochran is not an analogous art.

The newly amended Claim 21 is directed to a method of lowering plasma concentration of Lipoprotein(a) Lp(a). Therefore, prior art reference Chochran is not an analogous art because it does 1) does not pertain to solving the same problem as the current invention, and 2) it is not in the same field as the current invention.

Chochran disclosed a method directed to lowering the plasma level of **Low Density Lipoprotein (LDL)** in mammal. In contrast, the current invention is directed to a method in lowering the plasma level of **Lipoprotein(a) Lp(a)**. One of ordinary skill in the art would recognize that said inventions are **solving two distinct problems**. Although both inventions appeared to relate to Lipoprotein, a skilled artisan, at the time of filing, would recognize that methods effective in lowering LDL can inadvertently cause a raise in plasma level of Lp(a). See prior art reference “*HMG CoA reductase inhibitors lower*

LDL cholesterol without reducing Lp(a) levels " by Kostner et al. Line 21-24. A copy of said reference is attached for the Examiner to review.

Likewise, a skilled artisan would recognize that the two inventions are in different fields of technology.

In addressing the issue of what reference is pertinent to the field, the Court has stated that: [a] reference is reasonably pertinent if... it is one which, because of the matter with which it deals, logically would have commended itself to the inventor's attention in considering his problem..." *In re Clay*, 966 F.2d 656.

Here, lowering LDL lipoprotein is not in the same field as lowering plasma level of Lp(a) because a skilled artisan would logically have not consulted Cochran knowing that method to lower LDL can inadvertently raise the plasma level of Lp(a).

Without Cochran, current invention cannot be obvious in view of Rath et al. (US 5650418), Rath et al. (EP 0 891771 A1), and further in view of Product Information Brochure (Life Extension Mix Multivitamin, 1997) and Umbdenstock (US 5332579) because

For the above reasons, applicant respectfully submits that Chochran should not be considered as an analogous art to support the rejection of obviousness.

II. There is no motivation to combine the prior references because readily accessible references at the time of filing teach away from the claimed combination

In general, a reference teaches away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. *United States v. Adams*, 383 US 39.

Although a reference that teaches away is a significant factor to be considered in determining obviousness, the nature of the teaching is highly relevant and must be weighed in substance. *In re Gurley*, 31 USPQ 2d at 1132.

Applicant respectfully submits the following abstract of prior art references, all of which would have been easily retrievable at the time of filing, that teach away from the proposed combination by the Examiner:

- a. In "*HMG CoA reductase inhibitors lower LDL cholesterol without reducing Lp(a) levels*" by Kostner GM, published in 19989, effective method of lowering LDL level caused a raise in the plasma level of Lp(a). The article concludes that Lp(a) are cleared from the plasma differently from LDL.
- b. In "*The effect of genetic determination of low density lipoprotein levels of lipoprotein(a)*" by Hegele et Al, published in April 1991, the article concludes that Lp(a) level are not associated with the defect associated at the LDL receptor gene.
- c. In "*Lipoprotein (a) as an independent risk factor for myocardial infarction in patients with common hypercholesterolaemia*" by Watts et al, published in 1993 March, the article observed that while Lp(a) is directly linked to patients with myocardial infarction while LDL cholesterol level was found to not have a correlation with the disease.
- d. In "*Lipoprotein (A) in patients with coronary atherosclerosis*" by Olofinskaia et al, published in 1991 October, the article concludes that

there was no relation of LP(a) to total cholesterol,.....low and very low density lipoprotein cholesterol.....

The prevalent prior art references available to a skilled artisan at the time of filing not only suggest method of lowering LDL to be distinctly different than method of lowering Lp(a), they also suggest the potential adverse effect to the level of Lp(a) when employing method to lower LDL. This adverse teaching is highly relevant and must be weighed in substances.

Thus, a skilled artisan would not have been motivated to combine method of lowering LDL (Cochran) with the method of lowering Lp(a) in light of the teaching available to the ordinary skill in the art.

III. There was no reasonable expectation of success for the claimed combination.

As cited earlier, there exists prevalent prior art references available to a skilled artisan suggesting method of lowering LDL to be distinctly different than method of lowering Lp(a). Further, they implicate the potential adverse effect to the level of Lp(a) when employing method to lower LDL.

Since nothing in Rath (US' 418), Rath (EP'771), Cochran, Life Extension Mix, and Umbdenstock would indicate that combining methods of lowering LDL with method of lowering Lp(a) would be successful in lowering Lp(a), a skilled artisan has no reasonable expectation of success for the claimed combination.

Without indicating some reasonable expectation of success, the *prima facie* obviousness rejection is not established.

IV. The combined references do not teach or suggest the claimed limitation

Applicant further submits that even if Rath (US' 418), Rath (EP'771), Cochran, Life Extension Mix, and Umbdenstock were to be combined, they do not teach or suggest the claimed limitation of the current invention. Here, only Rath (US' 418) and Rath (EP'771) are directed to the method of lowering Lp(a). By combining the method of lowering LDL of Cochran and Umbdenstock, the claimed limitation of present invention for a method to lowering Lp(a) is not taught or suggested.

Applying the Graham factors, applicants respectfully submit that it would not have been obvious as a whole for a skilled artisan to derive the claimed invention from the combination of Rath (US' 418), Rath (EP'771), Cochran, Life Extension Mix, and Umbdenstock *knowing that method of lowering LDL is distinctly different than method of lowering Lp(a)* and that the is potential of adverse effect to the level of Lp(a) when employing method to lower LDL.

CONCLUSION

For at least the reasons set forth herein, Applicant respectfully submits that all the rejections have been overcome and all the pending claims are allowable. Accordingly, withdraw of the rejection and allowance of the present claims are requested. If the Examiner has any questions pertaining to this application or feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at (650) 941-1196.

Applicants respectfully request that a Notice of Allowance be issued in this case.

Respectfully submitted

By


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